

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

**OUTSOURCING FACILITIES
ASSOCIATION, ET AL.,**

Plaintiffs,

v.

No. 4:24-cv-00953-P

**UNITED STATES FOOD AND DRUG
ADMINISTRATION, ET AL.,**

Defendants.

STIPULATED PROTECTIVE ORDER

This Stipulated Protective Order (“Protective Order” or “Order”) is agreed to this 14th day of January, 2025, by the parties in the above-captioned case (the “Action”). The parties agree, and the Court orders, as follows:

1. For purposes of this Protective Order, the term “Confidential Information” means information that is part of the Administrative Record in this matter, and which:

- a. Was submitted to the U.S. Food and Drug Administration (“FDA”) by a party or third party who designated the information as confidential; or
- b. Is information subject to the Privacy Act, which limits disclosure of certain personal private information; or 18 U.S.C. § 1905, which limits disclosure of, *inter alia*, certain trade secret and confidential commercial information; or
- c. Is exempt from disclosure pursuant to 5 U.S.C. § 552(b).

2. No documents containing, referring to, or otherwise disclosing Confidential Information shall be publicly filed with the Court. Confidential Information shall be submitted to the Court under seal in accordance with Local Rule 79.3. Confidential Information may be filed

under seal pursuant to Local Rule 79.3(a) without a motion for leave to file under seal as required under Local Rule 79.3(b). Counsel for the filing party shall be responsible for serving a copy of all sealed documents and attachments on all other counsel of record.

3. Notwithstanding the above, documents that are part of the Administrative Record, including FDA's decision memorandum, "Resolution of Tirzepatide Injection Product Shortage and Supply Status," dated December 19, 2024, may be provided to the persons identified in § 4 with Confidential Information unredacted. FDA will mark each page of each such document as "Confidential, Subject to Protective Order." Persons who receive such documents subject to this Protective Order shall treat them as confidential according to its terms.

4. Confidential Information shall not be furnished, shown, or disclosed to any person except:

- a. The Court and court personnel;
- b. Employees, agents, and attorneys of FDA and the U.S. Department of Health and Human Services pursuant to their regulations and policies and in the normal course of business;
- c. Department of Justice attorneys assigned to this case, as well as those attorneys' supervisor(s) and supporting personnel; or
- d. Outside counsel of record for Plaintiffs and Intervenor-Defendant in this Action and outside counsel of record's supporting personnel and contract vendors, including but not limited to retained experts, paralegals, clerks, secretaries, IT personnel, copy vendors, and clerical personnel. This category does not include any attorney or other employee at outside counsels' firms who occupies any position at either of the plaintiff organizations.

5. Individuals who receive Confidential Information under this Protective Order shall use it only for purposes directly related to the prosecution or defense of this litigation, and shall not further disseminate or disclose it to any person not identified in § 4.

6. In the event that Plaintiffs or Intervenor-Defendant oppose a confidential designation of a particular document or documents within the Administrative Record, then all parties shall confer regarding the confidential designation and whether it may be removed from such document(s) altogether or may be removed subject to the redaction of specific information within the document(s). If the parties are unable to resolve any dispute regarding a confidential designation informally, the party opposing the designation may seek intervention by the Court to determine whether a confidentiality designation shall be overturned. The information shall be treated as confidential pending a ruling by the Court.

7. If Defendants inadvertently produce any documents containing Confidential Information without labeling or marking or otherwise designating it as such in accordance with the provisions of this Order, any party may later give written notice to the other parties that the document contains Confidential Information and should be treated as such in accordance with the provisions of this Protective Order. The parties must treat such documents with the noticed level of protection from the date such notice is received. Disclosure, prior to the receipt of such notice of such information, to persons not authorized to receive such information shall not be deemed a violation of this Order.

8. Within 60 days after the termination of this Action, including any appeals, Plaintiffs' and Intervenor-Defendant's counsel shall destroy all copies of documents that contain Confidential Information. The foregoing includes both documents produced as part of the Administrative Record and any other documents to the extent that they contain Confidential Information. Notwithstanding the above, counsel of record for each party may retain archival copies of all documents filed with the Court (regardless of whether such documents were filed under seal and including, without limitation, pleadings, motion papers and exhibits thereto, and joint appendices), all discovery responses, all

transcripts or other records of court proceedings, and all legal memoranda, legal correspondence, and attorney work product.

9. Notwithstanding any other provision herein, this Protective Order does not limit the right of a Plaintiff or Intervenor-Defendant to use, disclose, or retain its own Confidential Information (or, as applicable, the Confidential Information of its members).

10. The inadvertent or unintended disclosure of Confidential Information shall not be deemed a waiver in whole or in part of the claim of confidentiality for any Confidential Information.

11. The provisions of this Protective Order may be modified at any time by the Court (including after termination of this Action), upon its own motion or the motion of any party.

12. The provisions of this Protective Order shall take effect immediately.

13. Following the termination of this Action, the terms of this Protective Order shall continue to apply to any Confidential Information retained by any party.

14. The Court retains jurisdiction after the termination of this Action to enforce this Protective Order.

SO ORDERED on this **14th day of January 2025**.



MARK T. PITTMAN
UNITED STATES DISTRICT JUDGE